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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WINKLER, ULRIKE 15	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/670,105	Applicant(s) MONCANY ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-48* is/are pending in the application.

4a) Of the above claim(s) *29-31,34-37,40-42 and 45-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,28,32,33,38,39,43 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 and 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, covering claims 27, 28, 32, 33, 38, 39, 43 and 44, with SEQ ID NO: 48 and 51 and the viral strain HIV-Bru in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the office has not established a serious burden to search all groups and that similar subject matter has been examined together in related applications. This is not found persuasive because the instant invention is drawn to compositions that are obtained utilizing a PCR method, in order to evaluate the composition each primer pair must be searched in the prior art. Applicant has not provided any evidence that the search for one primer pair will necessarily cover the search for all the primers listed in the claims. The restriction between the peptides (class 530 subclass 300) and the antibodies (class 530 and subclass 389.1) is proper, although antibodies are proteins they have unique structures and require a separate search in the prior art as evidenced by their different classification. Polypeptides (class 530 subclass 300) are made up of amino acids while nucleotide sequences (class 536 subclass 23.72) are made up of nucleic acids, the search for one group will not be coextensive with the search for the other group in the prior art as evidenced by their different classification.

The requirement is still deemed proper and is therefore made FINAL.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 4 and 5, are attached to the instant Office Action. Note that paper No. 5 is a duplicate of paper No. 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 28, 32, 33, 38, 39, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins. The claimed polypeptides are described based on the method of obtaining the sequences of yet undiscovered and undisclosed polynucleotide sequences. Applicant's were in possession of the claimed sequences disclosed drawn to the specific viral strains disclosed in the specification HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521).

However, applicants were not in possession of yet undiscovered and mutated new viral strains as encompassed by the instant claims. The specification discloses a method of amplifying viral sequences utilizing oligonucleotide primers that are directed at highly conserved regions within the viral group comprising HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521). The claimed polypeptides are directed against those sequences which comprise the "hypervariable region" of the viral Env protein.

The claims encompass a genus of compounds defined only by their method of obtaining the compound wherein the relationship between the structural features of members of the genus and said method have not been defined. In the absence of such a relationship either disclosed in the as filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

Although the description does not provide working examples of the compounds, the description teaches a method for applying PCR to discover nucleotide sequences which encode undisclosed polypeptide fragments and the person skilled in the art can understand how to use the screening method considering the common general knowledge.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the invention. This may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the use of drawings or structural chemical formulas that show that the invention was complete, or describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

> A definition by function alone "does not suffice, to sufficiently describe a coding sequence because it is only an indication of what the gene does, rather than what it is." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998), the court affirmed a district court ruling that all of the claims of a patent were invalid because the specification did not provide an adequate written description of the rat DNA that was required by the asserted claims. The court said that "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 1 19 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1 171). "a mere wish or plan" for obtaining an invention is not enough to comply with § 1l2, ¶ 1(*Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 559, at 1566).

> It means little to "invent" a method if one does; not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, as defendants argue, akin to "inventing" a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone. Without possession of such a substance, such a cure is illusory, and there is no meaningful possessions of the method. (see 00-CV-6161, March 5th 2003 decision, United States District Court Western District of New York, Judge Larimer).

The claimed invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins. The claimed polypeptides are describes based on the method of obtaining sequences of yet undiscovered and undisclosed viral strains. The specification has only proved information regarding the following viral strains HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521). However, no structural information is provided regarding any other viral polypeptides, nor is there any indication that the artisan actually implemented the method of the claims to identify such polypeptides. This situation is analogous to that of *Regents of the University of California v Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention. The claim fails to comply with the written description requirement.

Claims 27, 28, 32, 33, 38, 39, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins. The specific strains of viruses diclsoed in the specification are HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521). The claimed polypeptides are describes based on the method of obtaining the sequences of yet undiscovered and undisclosed polypeptides.

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without

undue experimentation. The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. Such an analysis does not need to specifically enumerate (points 1-8) but only needs to have a select few of the factors present discussed in a rejection.

The specification shows oligonucleotide primers of conserved viral regions which can be used in methods of sequencing viral nucleic acids using PCR.

The claims meet the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C. § 101. In the instant cased the presence or absence of viral nucleic acids in patient samples is useful in diagnostic methods relating to HIV infection.

> It must be remembered, however, that"[p]atent protection is granted in return for an enabling disclosure sure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute an enabling disclosure." *Genentech. Inc.* v. *Novo Nordisk A/S,* 108 F83d 1361, 1365 (Fed. Cir.), cert denied, 522 U.S. 963 (1997) at 1366 (quoting *Brenner* v. *Manson,* 383 U.S. 519, 536 (1966) (stating, in context of the utility requirement that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"). Thus, while the need for some experimentation is by no means necessarily fatal, "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech. Inc.* v. *Novo Nordisk A/S,* 108 F83d 1361,(Fed. Cir.), cert denied, 522 U.S. 963 (1997).

The instant fact pattern fails to disclose any particular structure for the claimed polypeptide sequence of viral strains that are not disclosed in the instant specification, as the

PCR method amplifies those regions belonging to the "hypervariable region" (the regions with the greatest diversity of mutations) of the Env protein. The specification provides a method of screening for nucleotide sequences that encode proteins, however, the specification does not disclose the structure of the proteins belonging to viral strains and mutants other than those five (HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521)) disclosed in the specification without undue experimentation. Furthermore an assay for finding a product is not equivalent to a positive recitation of how to make such a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112 first paragraph. Therefore, the instant invention is not enabled for the peptide fragments and the pharmaceutical compositions comprising the peptide fragments.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 3/24/03